UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF TEXAS

SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	CRIMINAL NO. 5:14-CR-00926
	§	
Plaintiff	§	
	§	
V.	§	
	§	
VASCULAR SOLUTIONS, INC. and HOWARD C. ROOT	§	
	§	
	§	
Defendants.	§	

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO TRANSFER VENUE

Dated: December 9, 2014.

By: s/ John C. Richter
John C. Richter
Michael R. Pauzé
King & Spalding LLP
1700 Pennsylvania Avenue NW, Suite 200
Washington, DC 20006
(202) 737-0500

s/ Johnny Sutton
Johnny Sutton
Ashcroft Sutton Ratcliffe.
919 Congress Avenue, Suite 1500
Austin, TX
(512) 370-1800
Attorneys for Defendant Vascular Solutions, Inc.

By: s/ John W. Lundquist
John W. Lundquist (MN #65286)
Dulce J. Foster (MN#285419)
Kevin C. Riach (MN #389277)
Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402
(612) 492-7000
Attorneys for Defendant Howard Root

INTRODUCTION

By choosing the Western District of Texas as the venue for this prosecution, the government seeks to force a mid-size company and its CEO to defend themselves in a lengthy, costly, and extremely complex criminal trial far from where they reside, far from where most witnesses reside, and in an overburdened district facing a judicial emergency. Far from being based on the conduct at issue, the government's venue decision appears to have been driven by the fortuitous venue of a civil whistleblower suit (long since resolved).

The objective circumstances that should have driven the government's decision – the location of the conduct, the witnesses, and the defendants – point to a venue more than a thousand miles away, in Minnesota. The allegations in the Indictment focus on conduct that occurred overwhelmingly in Minnesota. More witnesses reside in Minnesota than in any other district. Defendant Vascular Solutions, Inc. ("VSI") maintains its headquarters in Minnesota. Most of the company's officers and employees reside there – including the company's founder and CEO, Defendant Howard Root. And the investigation was led by the Consumer Protection Branch of the Department of Justice, which is based in Washington, D.C. and is equipped to conduct investigations and prosecutions all over the country.[1] Indeed, much of the government's investigation was conducted in Minnesota.

Despite these circumstances, the government chose to initiate this prosecution in an overburdened district, which last year was the venue for more than *ten times* as many felony

[1]/ The Consumer Protection Branch ("CPB") is part of DOJ's Civil Division in Washington, D.C. Per the Division in which it is housed, CPB attorneys typically handle civil cases. They also have jurisdiction to initiate certain types of regulatory-based criminal cases, including actions involving alleged Food, Drug, and Cosmetic Act violations; deceptive trade practices (such as lottery fraud, immigration services fraud, and telemarketing fraud); offenses relating to food and dietary supplements (such as cases involving rodent and insect infestation, fish products manufactured under insanitary conditions, the unlawful use of new animal drugs in cows slaughtered for food, and cheese products manufactured in facilities contaminated with dangerous bacteria); offenses under the Consumer Product Safety Act (such as toys that contain potentially toxic materials); and violations pertaining to the illegal sale of fireworks and odometer fraud. *See generally* Department of Justice, Consumer Protection Branch, *available at* http://www.justice.gov/civil/consumer-protection-branch-home (last visited Dec. 4, 2014).

cases per judge than the District of Minnesota. The situation is so dire that the Administrative Office of the U.S. Courts has declared this District a "judicial emergency." This case plainly belongs in Minnesota, where it should have been initiated at the outset. For these reasons, and those stated below, the Defendants respectfully request that this Court transfer this criminal prosecution to the District of Minnesota.

We have conferred with counsel for the United States, who advise they do not agree with transfer to Minnesota.

BACKGROUND

I. Defendants Vascular Solutions, Inc. and Howard Root

VSI is a publicly-traded corporation that develops and manufactures innovative medical devices. (Affidavit of Gordon Weber ("Weber Aff.") ¶ 2.) The company maintains its principal place of business and corporate headquarters in Maple Grove, Minnesota, a suburb of Minneapolis. (Weber Aff. ¶ 3.) About 350 of VSI's approximately 450 employees live and work in Minnesota. (Weber Aff. ¶ 5.) The company employs approximately 95 field sales representatives throughout the United States who sell VSI's medical devices to hospitals and physicians. (Weber Aff. ¶ 6.) Defendant Howard Root, the company's co-founder, has been VSI's CEO since the company's inception in 1997. (Affidavit of Howard C. Root ("Root Aff.") ¶ 2.) Mr. Root and his wife reside in a suburb of Minneapolis. (Root Aff. ¶ 3 .)

Formed in 1997, and led by Mr. Root, VSI has invented, developed, and launched over 80 new medical devices since its inception. (Weber Aff. ¶ 7.) Its products generally comprise three types of devices: catheters, hemostats, and vein products, which are sold to cardiologists, radiologists, electro-physiologists, and vein practitioners. (Weber Aff. ¶ 7.) Over 85% of the Company's sales derive from catheters and hemostats, such as the Langston catheter (the only catheter in the U.S. to simultaneously measure pressure in the aorta and heart to measure aortic

valve stenosis), and the Twin-Pass catheter (the only catheter in the U.S. that offers two independent lumens in one coronary catheter). (Weber Aff. ¶ 8.) The remaining less than 15% of sales derive from various vein products, only one of which is a focus of the government's off-label promotion claims in this case: the Vari-Lase® endovenous laser console and associated "Short Kit" procedure kit. (Weber Aff. ¶ 9.)

II. The Vari-Lase Endovenous Laser System

The litigation of this matter will involve complex regulations and complicated facts, accordingly we estimate that the trial will take between 4-8 weeks. (*See* Affidavit of John W. Lundquist ("Lundquist Aff.") ¶ 2.) Among other things, medical evidence will be presented concerning the Vari-Lase system and how it works in the human body. Physicians use the Vari-Lase system to treat varicose veins. (Weber Aff. ¶ 10.) The legs have two networks of vein systems: the deep and superficial venous systems. (Weber Aff. ¶ 10.) The deep veins are closer to the bones, while the superficial veins, including the Great Saphenous Vein, are closer to the skin. (Weber Aff. ¶ 10.) The two systems run parallel to one another, and are linked by connecting veins called perforator veins. (Weber Aff. ¶ 10.) Varicose veins are enlarged saphenous or perforator veins caused by incompetent valves in the vein resulting in the pooling of blood in the lower extremity. (Weber Aff. ¶ 10.) They can cause itching, aching, swelling and, in severe cases, inflamed skin and open sores. (Weber Aff. ¶ 10.)

The Vari-Lase system allows physicians to treat varicose veins by creating a blood clot (or "thrombosis") inside the vein with laser energy, known as endovenous laser ablation. (Weber Aff. ¶ 11.) Broadly speaking, a physician inserts a thin laser fiber through an introducer sheath that is placed using a needle stick into the varicose vein, with no surgical incision. (Weber Aff. ¶ 11.) The physician then delivers laser energy to the tip of the fiber, slowly pulling the fiber back through the varicose vein and creating a blood clot that occludes the vein. (Weber Aff.

¶ 11.) Blood flow then is redirected to functioning veins. (Weber Aff. ¶ 11.) Due to the variety of procedures and circumstances in which its endovenous laser products can be used, Vascular Solutions has continually innovated and brought to market new versions of its Vari-Lase procedure kit designed to meet different physician needs. (Weber Aff. ¶ 12.) As part of these efforts, and in recognition that physicians were using Vari-Lase products to treat short vein segments, including perforator veins, Vascular Solutions, in around 2007, began developing the Short Kit. (Weber Aff. ¶ 12.)

The Short Kit works the same way as other Vari-Lase kits but contains a relatively short length sheath that makes it easier for physicians to treat short vein segments. (Weber Aff. ¶ 13.) Only about 1,800 Short Kits were sold nationwide; each retailed for less than $300. (Weber Aff. ¶ 13.) During this product's seven-year life, sales averaged less than $77,000 per year, contributing less than one-tenth of one percent to the company's sales total. (Weber Aff. ¶ 13.) More than two-thirds of the customers that bought Vari-Lase consoles never purchased a Short Kit. (Weber Aff. ¶ 13.) More than two-thirds of the company's sales representatives never sold a Short Kit, and sales force compensation from Short Kit sales constituted a miniscule portion of total sales force compensation – again, less than one-tenth of one percent. (Weber Aff. ¶ 13.)

The Food and Drug Administration ("FDA") has cleared the Vari-Lase system and kits "for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein, and for treatment of incompetence and reflux of superficial veins in the lower extremity." (Indictment ¶ 12.) The meaning of this language is just one of the complex issues this case will address. The Indictment alleges that the Vari-Lase system was not cleared for perforator use (Indictment ¶ 13); however, the treatment of perforator veins is within the terms of the clearance – and thus "on-label" – so long as the varicosities are "associated" with reflux in the adjacent Great Saphenous Vein.

III. The Indictment

The Indictment charges the Defendants with eight misdemeanor counts of introducing into interstate commerce Vari-Lase devices that were "adulterated" and "misbranded" under 21 U.S.C. § 331(a), and one count of conspiring to defraud FDA by essentially concealing this conduct under 18 U.S.C. §371. The conspiracy count appears to plead both a misdemeanor and a felony. The basis for all the charges is the allegation that the company promoted the Short Kit for treatment of perforator veins. According to the government, treatment of perforator veins was "off-label" – *i.e.*, outside the terms of FDA's clearance to market the device. (Indictment ¶ 13.) Off-label use by physicians is entirely lawful, commonplace, and indeed often represents a medically accepted standard of care. *See, e.g.*, U.S. Food and Drug Administration, Draft Guidance, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices 3 (2009). Yet the government's theory is that "off-label promotion" by the manufacturer, even if truthful, renders the device misbranded and adulterated through a complex chain of reasoning via a web of statutory and regulatory provisions.

The Indictment charges that the Vari-Lase devices were misbranded in that the company: (1) failed to submit a pre-market notification to FDA (in Maryland) regarding a significant change in the device's intended use;[2] and (2) sold the device with inadequate directions for use.[3] (Indictment ¶ 67.) It also charges that the devices were adulterated in that they lacked an

[2]/ The pre-market notification process, often referred to as the "510(k)" process after the section of the Food, Drug & Cosmetic Act that created it, allows a manufacturer to obtain FDA clearance to introduce into interstate commerce a medical device that "is substantially equivalent to another device" that has been legally marketed. 21 U.S.C. § 360c(f)(1). If a cleared device is "significantly changed or modified in design, components, method of manufacture, or intended use," a new 510(k) review is required. 21 C.F.R. § 807.81(a)(3). According to the government, promotion of an off-label use, even if truthful, creates a new "intended use," 21 C.F.R. § 801.4, which then requires the manufacturer to submit a new 510(k).

[3]/ Certain devices are deemed misbranded if they lack "adequate directions for use." 21 U.S.C. 352(f)(1). The government appears to interpret this provision as requiring manufacturers to add directions for an off-label use to the label if that use is "intended." In fact, VSI's directions for use for the devices at issue were adequate.

approved application for pre-market approval.[4] (Indictment ¶ 65.) Although the products were designed, developed, and manufactured in Minnesota, the government chose to charge the company and Mr. Root with making one console sale and three Short Kit sales in Austin, Texas. Indeed, the total of *all* sales of Short Kits that were ever sold in Texas amounted to $11,000. (Weber Aff. ¶ 15.)

Notably, the company sold more Short Kits in Connecticut than in any other state. (Weber Aff. ¶ 13.) Connecticut, however, is within the Second Circuit, which in 2012 recognized the First Amendment problems with the government's position and reversed a misbranding conviction based on so-called off-label promotion. *See United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012). In doing so, the Court construed "the misbranding provisions of the Food, Drug and Cosmetic Act ("FDCA") as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs." Indeed, the government secured an indictment against Glen Holden in related case no. 5:14-cr-00927, which is currently pending before this Court, for allegedly making false statements about his sales of the Short Kit *in Connecticut*. The government conspicuously did not seek charges regarding the actual sales by Holden, however – perhaps because it recognized the awkwardness of prosecuting someone in Texas for conduct that was lawful in Connecticut where it occurred.

Procedural History

On November 19, 2010, Desalle Bui, a former VSI employee whom the company believed had violated his non-competition agreement, filed a *qui tam* complaint against VSI under the False Claims Act in this District. Complaint, Case No. 1:10-cv-00883-SS (W.D. Tex. Nov. 19, 2010). It is not clear why Bui chose to file his complaint here; he was living in Gilbert,

[4]/ *See* 21 U.S.C. 351(f)(1)(B). The government's adulteration theory is also based on the notion that off-label promotion creates a new "intended use" that can require the device to undergo pre-market approval even if it has already been cleared through the pre-market notification process. (Pre-market approval is a more onerous form of pre-market review.)

Arizona when he filed the complaint and still lives there. (Weber Aff. ¶ 14.) Bui's theory was that VSI promoted the Short Kit off-label for the treatment of perforator veins and caused physicians to submit claims for payment that were "false or fraudulent" within the meaning of the False Claims Act. On December 12, 2012, the United States intervened, in part, in the civil case against VSI, alleging that VSI had violated the False Claims Act. The parties settled the civil lawsuit on July 28, 2014. The company did not admit liability. (Weber Aff. ¶ 14.)

Despite the civil settlement, the government continued to pursue this matter criminally. And though the grand jury sat in the Western District, many of the grand jury witnesses were questioned outside of the Western District and outside the presence of the grand jury itself, by the attorney from the Consumer Protection Branch. This questioning occurred in Illinois, Washington, and Minnesota. (Affidavit of Daniel Scott ("Scott Aff.") ¶ 4.)

ARGUMENT

"[I]t is the public policy of this Country that one must not arbitrarily be sent, without his consent, into a strange locality to defend himself against the powerful prosecutorial resources of the Government." *Dupoint v. United States*, 388 F.2d 39, 44 (5th Cir. 1967). By trying to hale a Minnesota company and a Minnesota resident into a courtroom in San Antonio, that is precisely what the government seeks to do here. The government's position cannot be reconciled with well-established venue principles.

I. TRANSFER IS APPROPRIATE FOR THE CONVENIENCE OF THE DEFENDANTS, THE WITNESSES, AND IN THE INTERESTS OF JUSTICE

The Court may transfer a criminal proceeding to another district "for the convenience of the parties and witnesses, and in the interests of justice." Fed. R. Crim. P. 21(b). Courts determine whether transfer is appropriate under Rule 21(b) by applying the factors announced in *Platt v. Minnesota Mining & Manufacturing. Co.*, 376 U.S. 240, 243-44 (1964):

> (1) location of . . . defendant; (2) location of possible witnesses; (3) location of events likely to be in issue; (4) location of documents and records likely to be involved; (5) disruption of defendant's business unless the case is transferred; (6) expense to the parties; (7) location of counsel; (8) relative accessibility of place of trial; (9) docket condition of each district or division involved; and (10) any other special elements which might affect the transfer.

See also, e.g., *United States v. Ubak-Offiong*, 364 Fed. App'x 859, 862-863 (5th Cir. 2010) (citing *Platt* factors); *United States v. Morris*, 176 F. Supp. 2d 668, 671-72 (N.D. Tex. 2001) (granting transfer motion based on application of *Platt* factors).

"Nothing in Rule 21(b) or in the cases interpreting it place[s] on the defendant seeking a change of venue the burden of establishing truly compelling circumstances for such a change. It is enough if, all relevant things considered, the case would be better off transferred to another district." *In re Balsimo*, 68 F.3d 185, 187 (7th Cir. 1995); *see also United States v. Benjamin*, 623 F. Supp. 1204, 1211 (D.D.C. 1985) ("This Court has liberally construed [Rule 21(b)] so as to minimize inconvenience to a defendant." (internal quotation omitted)).

The Court should transfer this case to the District of Minnesota in accordance with the 10 *Platt* factors, which can be grouped into three categories here: *First*, the central business decisions around the product at issue were made in Minnesota, not Texas. *Second*, trying this case in Texas would inflict substantial, unnecessary costs on the defendants, their attorneys, and

the witnesses. And *third*, judges in the Western District of Texas are laboring under a substantially more burdensome caseload than those in the District of Minnesota.

A. Minnesota was the Location of the Central Business Decisions About the Product at Issue.

"The proper venue for criminal actions is normally 'in the district in which the offense was committed.'" *Morrison*, 946 F.2d at 489 (quoting Fed. R. Crim. P. 18). When allegations of misconduct include events in multiple districts, the district that serves as the nexus for these events —the "nerve center" of the alleged crimes—should be the venue for trying the matter. *See, e.g.*, *United States v. Donato*, 866 F. Supp. 288, 293-294 (W.D. Va. 1994) (concluding that venue should be in district where defendants "hatched their alleged scheme [and] carried it out"); *United States v. Haley*, 504 F. Supp. 1124, 1128 (E.D. Pa. 1981) (transferring case from Pennsylvania to Georgia because "many of the overt acts described in the indictment purportedly occurred in Georgia" and Georgia "appears to be the 'nerve center' of the alleged illicit operations"); *United States v. Alter*, 81 F.R.D. 524, 526 (S.D.N.Y. 1979) (granting transfer from New York to Florida since most conduct in furtherance of the alleged scheme to defraud occurred in Miami, and Miami "was the 'nerve center' of the alleged illicit operations"); *see also United States v. Bein*, 539 F. Supp. 72, 74 (N.D. Ill. 1982) (same); *United States v. Atwood*, 538 F. Supp. 1206, 1209 (E.D. Pa. 1982) (same).

Similarly, in the specific context of a health care fraud or off-label promotion prosecution, the appropriate venue is the "hub" of the alleged conspiracy. *See, e.g.*, Memorandum and Order, *United States v. Arizant, Inc., et al.*, Case No. 03-30023, at 2 (S.D. Ill., Sept. 23, 2003) (granting transfer from Illinois to Minnesota, where "hub" of alleged health care fraud conspiracy existed) (attached as Exhibit A to the Affidavit of John W. Lundquist).

Here, the bulk of the conduct alleged in the Indictment occurred in Minnesota or as a result of VSI's corporate operations in Minnesota. VSI managed the sales representatives who

allegedly promoted the Short Kit off-label, and Mr. Root lived and worked in Minnesota throughout the relevant time. For example, the Indictment alleges that the following acts occurred in or from Minnesota:

- VSI decided not to resubmit the Short Kit for 510(k) approval by the FDA. (Indictment ¶ 23.)
- VSI and Mr. Root presented the results of the RELIEVE Study to the VSI Board of Directors. (Indictment ¶ 24.)
- VSI and Mr. Root developed and launched the marketing campaign to sell the Short Kit. (Indictment ¶¶ 26, 58.)
- VSI and Mr. Root conducted biannual National Sales Meetings where the sales force was allegedly instructed to promote the Short Kit off-label. (Indictment ¶¶ 29, 37, 42, 50.)
- VSI and Mr. Root conducted World Sales Meetings where the sales force was allegedly instructed to promote the Short Kit off-label. (Indictment ¶ 41, 51, 52.)
- VSI and Mr. Root developed sales meeting presentations that contained intentionally misleading information about the Short Kit. (Indictment ¶¶ 26-29, 47, 49, 51, 52, 58.)
- Mr. Root and VSI management directed VSI employees to promote the Short Kit off-label. (Indictment ¶¶ 30, 34(a), 35(a).)
- Mr. Root and VSI management reviewed employee "trip reports" and emails that revealed details about employees' off-label promotion of the Short Kit. (Indictment ¶¶ 30, 38, 39, 40, 53, 55, 57.)
- Mr. Root and VSI management drafted and sent emails to field sales employees commending their work promoting the Short Kit off-label and instructing employees to continue to make such sales. (Indictment ¶¶ 30, 38, 48.)
- VSI and Mr. Root "caused hundreds of shipments" of Vari-Lase devices intended for off-label use. (Indictment ¶ 36.)
- VSI and Mr. Root developed instructions and warnings concerning perforator use for the Vari-Lase labeling, but after failing to obtain FDA approval for perforator treatment nonetheless put similar instructions and warnings on the label substituting the words "short vein segments" for the words "perforator veins." (Indictment ¶ 58(g).)
- VSI and Mr. Root conducted a "sham investigation" of allegations that VSI had been selling Vari-Lase devices for unapproved uses. (Indictment ¶ 59.)

- VSI and Mr. Root actively concealed from the United States that VSI was continuing to sell devices for perforator use after it learned of the federal investigation of its business practices. (Indictment ¶ 61.)

To be sure, the Indictment alleges (and VSI vigorously disputes) that the defendants illegally sold one Vari-Lase console and three sets of Vari-Lase Short Kits in the Western District of Texas. (Indictment ¶¶ 65, 67.) And it identifies a few communications between one sales representative and two physicians in this District as evidence of the company's intent. (*See* Indictment ¶ 54.) The government's allegations are misleading at best. But, for purposes of this motion, the more important point is that the government's strained efforts to link this case to the Western District only highlight why venue is not appropriate here. VSI engaged in minimal sales activity in Texas: A total of only four customers purchased a total of 32 Short Kits in the Western District, which represents only 1.8% of the Short Kits sold in the United States. (Weber Aff. ¶ 15.) And, in any event, this case will not revolve around the specific sales of the Short Kit that took place in this District. Instead, it will involve complicated factual and legal questions about whether and in what circumstances the treatment of perforator veins is within the terms of the Vari-Lase system's clearance; whether the defendants engaged in speech promoting the off-label use of the Short Kit; whether the First Amendment protects that speech; and the interpretation and application of multiple provisions of the FDCA and FDA regulations. Nearly all of the allegedly inappropriate conduct that the Indictment identifies took place in Minnesota. Minnesota was the "nerve center" of the conduct at issue. To allow the location of a few arbitrarily-chosen Short Kit sales and one console sale to determine venue makes no sense.

B. The Defendants, Company Employees, and Key Witnesses Reside in Minnesota.

"Under Rule 21(b), the district court is to consider the convenience of the witnesses as well as the convenience of the parties." *United States v. Pry*, 625 F.2d 689, 691 (5th Cir. 1980). When a defendant resides outside the district in which he is being tried, transfer is often

appropriate. *Morris*, 176 F. Supp. 2d at 673. And when a majority of both the government and the defense witnesses reside outside the district, transfer is even more clearly warranted. *Id.*

That is the case here. Both Mr. Root and VSI are residents of Minnesota, and Mr. Root and his family live in the Minneapolis metropolitan area. (Weber Aff. ¶ 3; Root Aff. ¶ 3.) VSI was incorporated in Minnesota in 1996 and has been headquartered in the Minneapolis metropolitan area ever since. (Weber Aff. ¶ 3.) All of VSI's officers reside in Minnesota, and five of its seven Board members reside in Minnesota (with the other two residing in Illinois). (Weber Aff. ¶ 4.)

Attorneys for the defendants and many witnesses have no connection to the Western District. Most maintain their headquarters in Minneapolis; none has an office in the Western District of Texas.[5] Minnesota attorneys have represented Mr. Root and potential witnesses throughout the pre-indictment process. (Scott Aff. ¶ 2; Hopeman Aff. ¶ 2; Root Aff. ¶ 4.) When particular attorneys have represented a defendant throughout a pre-indictment investigation, their location is "highly significant" to the transfer decision. *United States v. Lima*, No. 94CR800, 1995 U.S. Dist. LEXIS 7796, at *9 (N.D. Ill. May 31, 1995).

The witnesses would face the same inconveniences. We are not aware of any residents of the Western District of Texas who testified before the grand jury or whom the government interviewed prior to indictment. Witnesses included:

- Susan Christian (Plymouth, Minnesota)
- Carrie Powers (Maple Grove, Minnesota)
- Fred Reuning (Minneapolis, Minnesota)
- Andrea Fenton Abbs (Minneapolis, Minnesota)
- Deborah Schmalz (Minneapolis, Minnesota)
- Elizabeth Dabruzzi (Minneapolis, Minnesota)
- Melissa Thielen (Minneapolis, Minnesota)
- John DeVito (Ballston Spa, New York)

[5] Several former VSI employees who testified before the grand jury and may be witnesses at trial are represented by counsel at Kelly, Wolter, and Scott, P.A. in Minneapolis. (Scott Aff. ¶ 1.) Current VSI employees who testified before the grand jury and may be witnesses at trial are represented by counsel at Felhaber Larson in Minneapolis. (Affidavit of Jon Hopeman "Hopeman Aff." ¶ 1.)

- Anthony Ramiro (Virginia Beach, Virginia)
- Elizabeth Matthews (Carmel, Indiana)
- Dr. Timothy Manoni (Stratford, Connecticut)
- Dr. Marsel Huribal (Stratford, Connecticut)
- Kathleen Davis Hall (Cleveland, Ohio)
- Christine Snyder (Chicago, Illinois)
- Anthony Jakubowski (Chicago, Illinois)
- Chris Harrelson (Rockwall, Texas)
- Shane Carlson (South Lake, Texas)
- Anthony Paszkeicz (Seattle, Washington)
- Richard Steitzer (Clifton Park, New York)
- Robert Lehoullier (Chichester, New Hampshire)
- Glen Holden (Pomfret Center, Connecticut)

(*See* Scott Aff. ¶ 2; Hopeman Aff. ¶ 2.)

The costs of and inconvenience to these witnesses in holding this trial in the Western District of Texas would thus be significant. "Travel and lodging expenses are an obvious factor to be considered in determining the balance of inconvenience to the parties." *Ferguson*, 504 F. Supp. at 1128-29. Trial here would require the defendants to pay for travel for attorneys, paralegals, officers, employees, and witnesses for a trial that could last over a month. (Weber Aff. ¶ 17.) The defendants expect that the costs of a trial lasting two months in the Western District of Texas would exceed that of a trial in Minnesota by more than $500,000. (*See* Lundquist Aff. ¶¶ 3-4.) Even the government would call only a small number of witnesses who reside in Texas, including one of the company's own employees.

Requiring VSI's officers and employees to travel constantly to and from Texas, moreover, would impede their ability to continue performing day-to-day work for the company. Running a company during a lengthy criminal trial will be challenging, but pales in comparison to doing so remotely from Texas. VSI's officers live in Minnesota, and at least three of them will be witnesses at trial. (Weber Aff. ¶ 4.) Many other VSI employees will either appear as witnesses or will be involved in preparing for and assisting with trial. When a "protracted trial which pins down key officials" may unnecessarily damage a company, transfer is warranted.

Benjamin, 623 F. Supp. at 1214; *see also United States v. Campestrini*, 993 F. Supp. 2d 69, 72 (D.P.R. 2014) (explaining that "disruption of [defendant's] business" due to travel requirements on principals weighs in favor of transfer); *United States v. Garza*, 593 F.3d 385, 390 (5th Cir. 2010) (observing that venue is inappropriate in a district when "[d]efendants, their witnesses, and their counsel all reside" outside of it). The Short Kit represented just one of VSI's more than 80 medical devices sold worldwide, and it made up a tiny percentage of VSI's total global sales. (Weber Aff. ¶¶ 7, 13.) VSI's other devices, not at issue in this case, include hemostats and catheters used to treat a wide range of serious medical conditions. (Weber Aff. ¶¶ 7-8.) Physicians and patients depend on VSI's innovative devices, which heightens the importance of avoiding unnecessary disruption to VSI's operations. *Cf. United States v. Kaluanya*, No. 09-cr-107-SM, 2009 U.S. Dist. LEXIS 93817, at *6-7 (D.N.H. 2009) (explaining that because physician witnesses would need to travel across the country for trial, burden on their patients weighed in favor of transfer).

C. The Primary Government Team Prosecuting this Case is from Main Justice in Washington, DC.

Against all of this, the "convenience of the prosecution" is *not* a factor to consider in deciding a motion to transfer venue. *United States v. Lipscomb*, 299 F.3d 303, 340 (5th Cir. 2002). Even if the government's convenience were relevant, a trial in Minnesota would impose few additional costs on the government. First, the principal government team initiating this case is from Main Justice in Washington, D.C. In fact, the government's Trial Attorney has traveled to Minnesota (and as far west as the state of Washington and as far east as the state of Connecticut) to question witnesses. Far fewer people—a small number of prosecutors and witnesses—would incur additional travel costs for a trial in Minnesota. The government would have no need to rent office space or equipment. The government is "ubiquitous," and "in any federal district, the government lawyers have a built in office, complete with logistical support

from parallel local staffs of the U.S. Attorney . . . and the F.B.I." *Benjamin*, 623 F. Supp. at 1212. *See also Ferguson*, 432 F. Supp. 2d at 567 ("It is true that Defendants are people of significant financial means, however, when compared to that of the government's resources, they pale in comparison."); *United States v. Coffee*, 113 F. Supp. 2d 751, 757 (E.D. Pa. 2000) ("The United States of America has, for all practical purposes, unlimited financial resources to bring to bear."); *Benjamin*, 623 F. Supp. at 1213 (explaining that "government lawyers . . . have nationwide responsibilities and are equipped to operate away from home with minimal disruption of their official business").

D. Given the Respective Caseloads, the District of Minnesota is Far Better Suited to Handle this Judicial Resource Intensive Prosecution.

Finally, transfer is appropriate because the Western District of Texas's caseload is far higher than that of the District of Minnesota. This is a complicated case. VSI has produced more than 2.1 million documents to the government, all from the Company's offices in Minnesota. More than a dozen individuals have provided grand jury testimony, and additional witnesses have been interviewed. A number of expert witnesses will be called to testify on medical and regulatory issues. Furthermore, this case will involve substantial briefing on complex constitutional and regulatory issues, including a motion to dismiss the misbranding counts for chilling the company's First Amendment right to speak truthfully about its product to medical professionals who have a legal duty to satisfy the standard of care for their patients.

Because it is not under a judicial emergency, the District of Minnesota is far better situated to handle the complicated pre-trial issues and trial. Between June 30, 2013, and June 30, 2014, each Western District of Texas judge heard more than *ten times* as many felony cases than his or her District of Minnesota counterpart: there were 523 felony cases filed per judgeship in the Western District of Texas, and 52 felony cases filed per judgeship in the District of

Minnesota.[6] The San Antonio division itself had more than three times as many criminal filings, 733, as did the entire District of Minnesota, 231. *See* Hon. Fred Biery, C.J., Fiscal Year 2014 Statistics: United States District Court Western District Texas at 7 (Oct. 14, 2014); *see also* Administrative Office of the United States Courts, Judicial Facts and Figures 2013 at Table 5.2, available at http://www.uscourts.gov/Statistics/JudicialFactsAndFigures/judicial-facts-figures-2013.aspx (last visited Dec. 8, 2014). As of June 30, 2014, there were 6,308 civil and felony criminal cases pending in this District and only 4,427 pending in the District of Minnesota.

The judicial vacancy in this District has been pending for over five years. The situation has grown so dire that the Western District vacancy has been declared a "judicial emergency" by the Administrative Office of the U.S. Courts. *Judicial Emergencies*, United States Courts Website, http://www.uscourts.gov/JudgesAndJudgeships/JudicialVacancies/JudicialEmergencies.aspx (last visited Dec. 8, 2014).

In an attempt to alleviate the Western District's overwhelming caseload, Senior Judge David Alan Ezra relocated from the District of Hawaii to the Western District in late 2012, as Western District judges were "swamped" with "immigration and drug cases on top of a busy civil caseload." Guillermo Contreras, *Hawaiian Judge Coming to Alamo City*, San Antonio Express-News, Dec. 25, 2012 (Lundquist Aff. Ex. B). As Chief District Judge Fred Biery explained in early 2013, "We are pedaling as fast as we can on an increasingly rickety bicycle." Gary Martin, *Vacancies, Backlogs Plague Federal Judiciary*, Hous. Chron., Mar. 1, 2013 (Lundquist Aff. Ex. C). An August 2013 ABA report on the state of the federal judiciary concluded that the Western District was one of five federal districts "laboring at near breaking

[6]/ *See Federal Court Management Statistics*, United States Courts Website, http://www.uscourts.gov/viewer.aspx?doc=/uscourts/Statistics/FederalCourtManagementStatistics/2014/district-fcms-profiles-june-2014.pdf&page=37 (last visited Dec. 8, 2014).

point levels of caseloads." *See* ABA House of Delegates Resolution & Report, Aug. 12, 2013 (Lundquist Aff. Ex. D).

There is no end in sight to the Western District backlog.[7] Western District Judge Lee Yeakel recently explained that even if a new judge is finally confirmed to fill the District's long-standing vacancy, there will still be a shortage of judges in the District. Jazmine Ulloa, *Texas Federal Judges Sound Alarm Over Empty Judicial Posts*, Austin-Am. Statesman, June 15, 2014 (Lundquist Aff. Ex. E). Despite Judge Ezra's relocation, the District has had "the second-highest number of criminal felony filings per judge in the country and the highest number of overall filings per judge of the seven districts with the most similar urban populations and number of judges—more than 940 last year compared with an average of roughly 670, according to the latest federal statistics." *Id.* It is no surprise that Judge Yeakel recently told the Austin-American Statesman, "We are underwater here . . . . We need new federal judges by every objective standard, and that's not what we are getting." *Id.*

By comparison, there is no judicial vacancy in the District of Minnesota, and it is not burdened by the same staffing and resource shortages that the Western District confronts as it seeks to tame its expanding caseload. As explained above, this case has no real nexus to this District in the first place, and given the dire condition of this District's docket, there is no good reason for this case to remain here when the District of Minnesota has the capacity to absorb this case without difficulty.

CONCLUSION

The Court should transfer this case to the District of Minnesota.

[7]/ We understand that U.S. Attorney Robert Pittman has been nominated for a judgeship in the Western District and is pending confirmation. However, he presumably would not be able to hear the case since he is the U. S. Attorney of record on the Indictment.

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By: s/ John C. Richter
John C. Richter
Michael R. Pauzé
King & Spalding LLP
1700 Pennsylvania Avenue NW
Suite 200
Washington, DC 20006
(202) 737-0500
Attorneys for Defendant Vascular Solutions, Inc.

s/ Johnny Sutton
Johnny Sutton
Ashcroft Sutton Ratcliffe.
919 Congress Avenue, Suite 1500
Austin, TX
(512) 370-1800

By: s/ John W. Lundquist
John W. Lundquist (MN #65286)
Dulce J. Foster (MN#285419)
Kevin C. Riach (MN #389277)
Fredrikson & Byron, P.A.
200 South Sixth Street
Suite 4000
Minneapolis, MN 55402
(612) 492-7000
Attorneys for Defendant Howard Root